

Complete Summary

GUIDELINE TITLE

Urinary incontinence: the management of urinary incontinence in women.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 221 p. [960 references]

GUIDELINE STATUS

This is the current release of the guideline.

Clinical guidelines commissioned by National Institute for Health and Clinical Excellence (NICE) are published with a review date 4 years from the date of publication. Reviewing may begin earlier than 4 years if significant evidence that affects guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

COMPLETE SUMMARY CONTENT

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 METHODOLOGY - including Rating Scheme and Cost Analysis
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SCOPE

DISEASE/CONDITION(S)

Urinary incontinence (UI) including:

- Stress UI
- Overactive bladder (OAB) with or without urge UI
- Mixed UI

Note: UI is defined as "the complaint of any involuntary urinary leakage." This guideline does not address the management and treatment of co-morbidities (such as pelvic organ prolapse, except where they relate to the treatment of urinary incontinence and/or overactive bladder syndrome), incontinence caused by neurological disease, incontinence in men, incontinence in children, or anal incontinence.

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Physical Medicine and Rehabilitation
Surgery
Urology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Nurses
Occupational Therapists
Patients
Physical Therapists
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

This clinical guideline has been developed with the aim of providing guidance on:

- Initial and ongoing assessments and investigations
- Appropriate use of conservative and surgical treatment options
- The competence required by surgeons performing the primary and subsequent operative procedures

TARGET POPULATION

- Women with urinary incontinence
- Women with overactive bladder syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. History taking and physical examination
2. Digital assessment of pelvic floor muscle contraction
3. Assessment of prolapse
4. Urine testing, including dipstick (blood, glucose, protein, leucocytes and nitrites) and midstream culture
5. Measurement of post-void residual urine volume, including bladder scan and catheterization
6. Referral to specialist
7. Symptom scoring and quality of life (QOL) assessment
8. Bladder diary
9. Urodynamic testing, if appropriate

Management/Treatment

1. Lifestyle interventions, including weight loss, caffeine reduction
 - Caffeine reduction
 - Modification of fluid intake
 - Weight loss
2. Physical therapies
 - Pelvic floor muscle training
 - Biofeedback
 - Electrical stimulation
3. Behavioral therapies, including bladder training programs
4. Drug therapies
 - Antimuscarinic drug therapy
 - Propiverine
 - Desmopressin
 - Intravaginal estrogens
5. Non-therapeutic interventions
 - Absorbent products, hand-held urinals, and toileting aids
 - Bladder catheterization (intermittent or indwelling urethral or suprapubic)
 - Intravaginal and intraurethral devices
6. Preventive use of conservative therapies
 - Pelvic floor muscle training during pregnancy
7. Surgical procedures for overactive bladder
 - Sacral nerve stimulation
 - Augmentation cystoplasty
 - Urinary diversion
 - Bladder wall injection with botulinum toxin A
8. Surgical procedures for stress urinary incontinence
 - Retropubic mid-urethral tape procedures
 - Open colposuspension
 - Autologous rectus fascial sling
 - Synthetic slings
 - Laparoscopic colposuspension
 - Intramural bulking agents

MAJOR OUTCOMES CONSIDERED

- Changes in symptoms
- Patient satisfaction

- Generic and incontinence-specific aspects of quality of life (QOL)
- Urodynamic investigation
- Quantification of incontinence
- Harm (adverse effects, surgical complications)
- Health economic outcomes, for example quality-adjusted life years

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the clinical questions was identified by systematic search strategies. The questions are shown in Appendix B in the original full-length guideline document.

Additionally, stakeholder organisations were invited to submit evidence for consideration by the guideline development group (GDG) provided it was relevant to the clinical questions and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical questions formulated and agreed by the GDG were executed using the following databases via the 'Ovid' platform: Medline (1966 onwards), Embase (1980 onwards), Cumulative Index to Nursing and Allied Health Literature (1982 onwards), British Nursing Index (1985 onwards) and PsycINFO (1967 onwards). The most recent search conducted for the three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects) was Quarter 1, 2006. The Allied and Complementary Medicine Database (AMED) was also used for alternative therapies (1985 onwards via the Datastar platform). Searches to identify economic studies were undertaken using the above databases and the National Health Service Economic Evaluations Database (NHS EED).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were not applied to searches. Both generic and specially developed methodological search filters were used appropriately.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

Towards the end of the guideline development process, searches were updated and re-executed, thereby including evidence published and included in the databases up to 17 March 2006. Any evidence published after this date was not included. This date should be considered the starting point for searching for new evidence for future updates to this guideline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

Level	Source of Evidence
1++	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1+	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias
1-	High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs) or RCTs with a very low risk of bias
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example case reports, case series)
4	Expert opinion, formal consensus

Levels of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia	Systematic review (with homogeneity) ^a of level-1 studies ^b
Ib	Level-1 studies ^b

II	Level-2 studies ^c ; systematic reviews of level-2 studies
III	Level-3 studies ^d ; systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or 'first principles'

^a Homogeneity means there are minor or no variations in the directions and degrees of results between individual studies that are included in the systematic review.

^b Level-1 studies are studies that use a blind comparison of the test with a validated reference standard ('gold' standard) in a sample of patients that reflects the population to whom the test would apply.

^c Level-2 studies are studies that have only one of the following:

- Narrow population (the sample does not reflect the population to whom the test would apply)
- Use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')
- The comparison between the test and reference standard is not blind
- Case-control studies

^d Level-3 studies are studies that have at least two or three of the features listed above.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesis of Clinical Effectiveness Evidence

Evidence relating to clinical effectiveness was reviewed using established guides and classified using the established hierarchical system shown above in the "Rating Scheme for the Strength of the Evidence." This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study receives a quality rating coded as '++', '+' or '-'. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs; EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as '-'. Usually, studies rated as '-' should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2). A level of evidence was assigned to each study, and to the body of evidence for each question.

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example if a systematic review, meta-analysis or RCT

existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was optimal.

The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting diagnostic tests of accuracy. In the absence of a validated ranking system for this type of test, National Institute for Health and Clinical Excellence (NICE) has developed a hierarchy for evidence of accuracy of diagnostic tests that takes into account the various factors likely to affect the validity of these studies (shown above in "Rating Scheme for the Strength of the Evidence.").

For economic evaluations, no standard system of grading the quality of evidence exists. Economic evaluations that are included in the review have been assessed using a quality assessment checklist based on good practice in decision-analytic modelling.

Evidence was synthesised qualitatively by summarising the content of identified papers in evidence tables and agreeing brief statements that accurately reflected the evidence. Quantitative synthesis (meta-analysis) was performed where appropriate. Where confidence intervals were calculated, this was done in accordance with accepted methods. Summary results and data are presented in the guideline text.

Specific Considerations for this Guideline

It was anticipated that some evidence relevant to this guideline would not be specific to women with urinary incontinence (UI) and thus studies with mixed populations (men and women, and/or with UI of different aetiology) were considered if the majority of the population was women with idiopathic UI or overactive bladder (OAB).

Published guidance from the NICE Interventional Procedures (IP) Programme was considered, alongside all relevant evidence in women with UI or OAB when an interventional procedure was approved for use. Where the IP guidance states that an interventional procedure is not for routine use, the procedure was not considered within this guideline.

The NICE health technology appraisal on tension-free vaginal tape (2003) was updated within this guideline by addressing a question on the intervention. The associated NICE guidance will be withdrawn on publication of this guideline.

The classification of adverse effect frequency used by the Medicines and Healthcare products Regulatory Agency (MHRA) was adopted within the guideline, as shown in Table 1.3 in the original full-length guideline document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Expert Consensus (Delphi)
Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Forming and Grading Recommendations

For each guideline question, recommendations were derived using, and explicitly linked to, the evidence that supported them. In the first instance, informal consensus methods were used by the Guideline Development Group (GDG) to agree evidence statements and recommendations. Additionally, in areas where no substantial evidence existed, the GDG considered other guidelines or consensus statements to identify current best practice. Shortly before the consultation period, formal consensus methods were used to agree guideline recommendations (modified Delphi technique) and to select five to ten key priorities for implementation (nominal group technique).

Each recommendation was graded according to the level of evidence upon which it was based, using the established systems described below in the "Rating Scheme for the Strength of the Recommendations." For issues of therapy or treatment, the best possible level of evidence (a systematic review or meta-analysis or an individual RCT) equates to a grade A recommendation. For issues of prognosis, the best possible level of evidence (a cohort study) equates to a grade B recommendation. However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of relevant evidence.

In addition, the GDG made research recommendations in areas where evidence is lacking.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification (Grading) of Recommendations for Intervention Studies

Grade	Evidence
A	<ul style="list-style-type: none">• At least one meta-analysis, systematic review or randomised controlled trial (RCT) that is rated as 1++, and is directly applicable to the target population, or• A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, or• Evidence drawn from a National Institute for Health and Clinical Excellence (NICE) technology appraisal
B	<ul style="list-style-type: none">• A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results, or

Grade	Evidence
	<ul style="list-style-type: none"> Extrapolated evidence from studies rated as 1++ or 1+
C	<ul style="list-style-type: none"> A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, or Extrapolated evidence from studies rated as 2++
D	<ul style="list-style-type: none"> Evidence level 3 or 4, or Extrapolated evidence from studies rated as 2+, or Formal consensus
D (GPP)	<ul style="list-style-type: none"> A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group.

Classification (Grading) of Recommendations for Studies of the Accuracy of Diagnostic Tests

Grade	Level of Evidence
A (DS)	Studies with level of evidence Ia or Ib
B (DS)	Studies with level of evidence of II
C (DS)	Studies with level of evidence of III
D (DS)	Studies with level of evidence of IV

DS, diagnostic study

COST ANALYSIS

The aims of the economic input into the guideline were to inform the Guideline Development Group (GDG) of potential economic issues relating to urinary incontinence (UI) in women and to ensure that recommendations represent a cost effective use of healthcare resources.

The health economist helped the GDG by identifying topics within the guideline that might benefit from economic analysis, reviewing the available economic evidence and, where necessary, conducting economic analysis. Reviews of published health economic evidence are presented alongside the reviews of clinical evidence, and modelling is presented in the appendices in the original guideline document, with cross references from the relevant chapters:

- Appendix D: Economic evidence for urodynamics
- Appendix E: Costing first-line conservative treatment for urinary incontinence
- Appendix F: Cost effectiveness analysis for duloxetine

- Appendix G: A partial cost-consequence analysis for surgical treatment options for over active bladder (OAB)

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evidence categories for intervention studies (1++ through 4), evidence categories (Ia-IV) for studies of the accuracy of diagnostic tests, and recommendation grades (A-D) are defined at the end of the "Major Recommendations" field.

In addition to evidence-based recommendations, the guideline development group (GDG) also identifies good practice points (GPPs).

Assessment and Investigation

History Taking and Physical Examination

D (GPP) - At the initial clinical assessment, the woman's urinary incontinence (UI) should be categorised as stress urinary incontinence (SUI), mixed UI, or urge UI/overactive bladder (OAB). Initial treatment should be started on this basis. In mixed UI, treatment should be directed towards the predominant symptom.

D (GPP) - The clinical assessment should seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigation and treatment.

Pelvic Floor Muscle Assessment

D (GPP) - Routine digital assessment of pelvic floor muscle contraction should be undertaken before the use of supervised pelvic floor muscle training for the treatment of UI.

Assessment of Prolapse

D (GPP) - Women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus should be referred to a specialist.

Urine Testing

D (GPP) - A urine dipstick test should be undertaken in all women presenting with UI to detect the presence of blood, glucose, protein, leucocytes and nitrites in the urine.

D (GPP) - Women with symptoms of urinary tract infection (UTI) whose urine tests positive for both leucocytes and nitrites should have a midstream urine specimen sent for culture and analysis of antibiotic sensitivities. An appropriate course of antibiotic treatment should be prescribed pending culture results.

D (GPP) - Women with symptoms of UTI whose urine tests negative for either leucocytes or nitrites should have a midstream urine specimen sent for culture and analysis of antibiotic sensitivities. The healthcare professional should consider the prescription of antibiotics pending culture results.

D (GPP) - Women who do not have symptoms of UTI, but whose urine tests positive for both leucocytes and nitrites, should not be offered antibiotics without the results of midstream urine culture.

B (DS) - Women who do not have symptoms of UTI and whose urine tests negative for either leucocytes or nitrites are unlikely to have UTI and should not have a urine sample sent for culture.

Assessment of Residual Urine

B (DS) - The measurement of post-void residual volume by bladder scan or catheterisation should be performed in women with symptoms suggestive of voiding dysfunction or recurrent UTI.

D (GPP) - A bladder scan should be used in preference to catheterisation on the grounds of acceptability and lower incidence of adverse events.

D (GPP) - Women who are found to have a palpable bladder on bimanual or abdominal examination after voiding should be referred to a specialist.

Referral

D (GPP) - Women with UI who have any of the following should receive an urgent* referral:

- Microscopic haematuria** in women aged 50 years and older

- Visible haematuria
- Recurrent or persisting UTI associated with haematuria in women aged 40 years and older
- Suspected malignant mass arising from the urinary tract

Indications for referral are:

- Symptomatic prolapse that is visible at or below the vaginal introitus ("Assessment of Prolapse" section above)
- The finding of a palpable bladder on bimanual or abdominal examination after voiding ("Assessment of Residual Urine" section above).

In women with UI, further indications for consideration for referral to a specialist service include:

- Persisting bladder or urethral pain
- Clinically benign pelvic masses
- Associated faecal incontinence
- Suspected neurological disease
- Symptoms of voiding difficulty
- Suspected urogenital fistulae
- Previous continence surgery
- Previous pelvic cancer surgery
- Previous pelvic radiation therapy

*NICE's [Referral Guidelines for Suspected Cancer](#) define urgent referral as the patient being seen within the national target for urgent referrals (currently 2 weeks).

**Haematuria visible with the aid of a microscope.

Symptom Scoring and Quality of Life Assessment

D (GPP) - The following incontinence-specific quality of life scales are recommended when therapies are being evaluated: International Consultation on Incontinence questionnaire (ICIQ), Bristol Female Lower Urinary Tract Symptoms (questionnaire) (BFLUTS), Incontinence Quality of Life (questionnaire) (I-QOL), Stress and Urge Incontinence Quality of Life questionnaire (SUIQQ), Urinary Incontinence Severity Score (UISS), SEAPI-QMM incontinence classification system, Incontinence Severity Index (ISI), and King's Health Questionnaire (KHQ).

Bladder Diaries

D (GPP) - Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a minimum of 3 days of the diary, covering variations in their usual activities, such as both working and leisure days.

Pad Testing

D - Pad tests are not recommended in the routine assessment of women with UI.

Urodynamic Testing

D - The use of multichannel cystometry, ambulatory urodynamics or videourodynamics is not recommended before starting conservative treatment.

D - For the small group of women with a clearly defined clinical diagnosis of pure stress UI, the use of multichannel cystometry is not routinely recommended.

D (GPP) - Multichannel filling and voiding cystometry is recommended in women before surgery for UI if:

- There is clinical suspicion of detrusor overactivity
- There has been previous surgery for stress incontinence or anterior compartment prolapse
- There are symptoms suggestive of voiding dysfunction

Ambulatory urodynamics or videourodynamics may also be considered in these circumstances.

Other Tests of Urethral Competence

D - The Q-tip, Bonney, Marshall and Fluid-Bridge tests are not recommended in the assessment of women with UI.

Cystoscopy

D (GPP) - Cystoscopy is not recommended in the initial assessment of women with UI alone.

Imaging

D - Imaging (magnetic resonance imaging, computed tomography, X-ray) is not recommended for the routine assessment of women with UI. Ultrasound is not recommended other than for the assessment of residual urine volume.

Conservative Management

Lifestyle Interventions

D - A trial of caffeine reduction is recommended for the treatment of women with OAB.

D (GPP) - Consider advising modification of high or low fluid intake for the treatment of women with UI or OAB.

D - Women with UI or OAB who have a body mass index greater than 30 should be advised to lose weight.

Physical Therapies

A - A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI.

A - Pelvic floor muscle training programmes should comprise at least eight contractions performed three times per day.

D (GPP) - If pelvic floor muscle training is beneficial, an exercise programme should be maintained.

A - Perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training.

D - Electrical stimulation should not routinely be used in the treatment of women with OAB.

A - Electrical stimulation should not routinely be used in combination with pelvic floor muscle training.

D (GPP) - Electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy.

Behavioural Therapies

A - Bladder training lasting for a minimum of 6 weeks should be offered as first-line treatment to women with urge or mixed UI.

A - If women do not achieve satisfactory benefit from bladder training programmes, the combination of an antimuscarinic agent with bladder training should be considered if frequency is a troublesome symptom.

A - In women with UI who also have cognitive impairment, prompted and timed voiding toileting programmes are recommended as strategies for reducing leakage episodes.

Drug Therapies

A - Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed UI as first-line antimuscarinic drug treatment if bladder training has been ineffective. If immediate release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium or an extended release or transdermal formulation of oxybutynin should be considered as alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs.

D (GPP) - An early treatment review should be undertaken following any change in antimuscarinic drug therapy.

A - Propiverine should be considered as an option to treat frequency of urination in women with OAB, but is not recommended for the treatment of UI.

A - Flavoxate, propantheline and imipramine should not be used for the treatment of UI or OAB in women.

A - The use of desmopressin may be considered specifically to reduce nocturia in women with UI or OAB who find it a troublesome symptom.

However, the use of desmopressin for nocturia in women with idiopathic UI is outside the UK marketing authorisation for the product. Informed consent to treatment should be obtained and documented.

A - Duloxetine is not recommended as a first-line treatment for women with predominant stress UI. Duloxetine should not routinely be used as a second-line treatment for women with stress UI, although it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, women should be counselled about its adverse effects.

A - Systemic hormone replacement therapy is not recommended for the treatment of UI.

A - Intravaginal oestrogens are recommended for the treatment of OAB symptoms in postmenopausal women with vaginal atrophy.

Non-Therapeutic Interventions

D (GPP) - Absorbent products, hand-held urinals and toileting aids should not be considered as a treatment for UI. They should be used only as:

- A coping strategy pending definitive treatment
- An adjunct to other ongoing therapy
- Long-term management of UI only after treatment options have been explored

D (GPP) - Bladder catheterisation (intermittent or indwelling urethral or suprapubic) should be considered for women in whom persistent urinary retention is causing incontinence, symptomatic infections or renal dysfunction, and in whom this cannot otherwise be corrected. Healthcare professionals should be aware, and explain to women, that the use of indwelling catheters in urge UI may not result in continence.

C - Intermittent urethral catheterisation should be used for women with urinary retention who can be taught to self-catheterise or who have a carer who can perform the technique.

D (GPP) - Careful consideration should be given to the impact of long-term indwelling urethral catheterisation. The practicalities, benefits and risks should be discussed with the patient or, if appropriate, her carer. Indications for the use of long-term indwelling urethral catheters for women with UI include:

- Chronic urinary retention in women who are unable to manage intermittent self-catheterisation

- Skin wounds, pressure ulcers or irritations that are being contaminated by urine
- Distress or disruption caused by bed and clothing changes
- Where a woman expresses a preference for this form of management

D (GPP) - Indwelling suprapubic catheters should be considered as an alternative to long-term urethral catheters. Healthcare professionals should be aware, and explain to women, that they may be associated with lower rates of symptomatic UTI, "bypassing" and urethral complications than indwelling urethral catheters.

D (GPP) - Intravaginal and intraurethral devices are not recommended for the routine management of UI in women. Women should not be advised to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise.

Complementary Therapies

D - Complementary therapies are not recommended for the treatment of UI or OAB.

Preventive Use of Conservative Therapies

A - Pelvic floor muscle training should be offered to women in their first pregnancy as a preventive strategy for UI.

Surgical Management

D (GPP) - Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's childbearing wishes.

Procedures for Overactive Bladder

D - Sacral nerve stimulation is recommended for the treatment of UI due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended.

D (GPP) - Augmentation cystoplasty for the management of idiopathic detrusor overactivity should be restricted to women who have not responded to conservative treatments and who are willing and able to self-catheterise. Preoperative counselling should include common and serious complications: bowel disturbance, metabolic acidosis, mucus production and/or retention in the bladder, UTI and urinary retention. The small risk of malignancy occurring in the augmented bladder should also be discussed. Life-long follow-up is recommended.

D (GPP) - Urinary diversion should be considered for a woman with OAB only when conservative treatments have failed, and if sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Life-long follow-up is recommended.

D - Bladder wall injection with botulinum toxin A should be used in the treatment of idiopathic detrusor overactivity only in women who have not responded to conservative treatments and who are willing and able to self-catheterise. Women should be informed about the lack of long-term data. There should be special arrangements for audit or research.

The use of botulinum toxin A for this indication is outside the UK marketing authorization for the product. Informed consent to treatment should be obtained and documented.

D - Botulinum toxin B is not recommended for the treatment of women with idiopathic OAB.

Procedures for Stress Urinary Incontinence

A - Retropubic mid-urethral tape procedures using a "bottom-up" approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.

D - Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided women are made aware of the lack of long-term outcome data.

D - Synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction are not recommended for the treatment of stress UI.

D - Intramural bulking agents (glutaraldehyde cross-linked collagen, silicone, carbon coated zirconium beads or hyaluronic acid/dextran copolymer) should be considered for the management of stress UI if conservative management has failed. Women should be made aware that:

- Repeat injections may be required to achieve efficacy
- Efficacy diminishes with time
- Efficacy is inferior to that of retropubic suspension or sling

D - In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended.

D (GPP) - Laparoscopic colposuspension is not recommended as a routine procedure for the treatment of stress UI in women. The procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI.

A - Anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall– Marchetti–Krantz procedure are not recommended for the treatment of stress UI.

D - Autologous fat and polytetrafluoroethylene used as intramural bulking agents are not recommended for the treatment of stress UI.

For recommendations on the "Competence of Surgeons Performing Operative Procedures for Urinary Incontinence in Women" please refer to the original full-length guideline document.

Definitions:

Levels of Evidence for Intervention Studies

Level	Source of Evidence
1++	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1+	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias
1-	High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs) or RCTs with a very low risk of bias
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example case reports, case series)
4	Expert opinion, formal consensus

Levels of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia	Systematic review (with homogeneity) ^a of level-1 studies ^b
Ib	Level-1 studies ^b
II	Level-2 studies ^c ; systematic reviews of level-2 studies
III	Level-3 studies ^d ; systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or 'first principles'

^a Homogeneity means there are minor or no variations in the directions and degrees of results between individual studies that are included in the systematic review.

^b Level-1 studies are studies that use a blind comparison of the test with a validated reference standard ('gold' standard) in a sample of patients that reflects the population to whom the test would apply.

^c Level-2 studies are studies that have only one of the following:

- Narrow population (the sample does not reflect the population to whom the test would apply)
- Use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')
- The comparison between the test and reference standard is not blind
- Case-control studies

^d Level-3 studies are studies that have at least two or three of the features listed above.

Classification (Grading) of Recommendations for Intervention Studies

Grade	Evidence
A	<ul style="list-style-type: none"> • At least one meta-analysis, systematic review or randomised controlled trial (RCT) that is rated as 1++, and is directly applicable to the target population, or • A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, or • Evidence drawn from a National Institute for Health and Clinical Excellence (NICE) technology appraisal
B	<ul style="list-style-type: none"> • A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results, or • Extrapolated evidence from studies rated as 1++ or 1+
C	<ul style="list-style-type: none"> • A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, or • Extrapolated evidence from studies rated as 2++
D	<ul style="list-style-type: none"> • Evidence level 3 or 4, or • Extrapolated evidence from studies rated as 2+, or • Formal consensus
D (GPP)	<ul style="list-style-type: none"> • A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group.

Classification (Grading) of Recommendations for Studies of the Accuracy of Diagnostic Tests

Grade	Level of Evidence
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Grade	Level of Evidence
A (DS)	Studies with level of evidence Ia or Ib
B (DS)	Studies with level of evidence of II
C (DS)	Studies with level of evidence of III
D (DS)	Studies with level of evidence of IV

DS, diagnostic study

CLINICAL ALGORITHM(S)

A clinical algorithm for the management of urinary incontinence in women is provided in the original full-length guideline document.

There following algorithms are available in the NICE version of the guideline (see "Availability of Companion Documents" field in this summary.)

- Women with UI or OAB
- Stress UI
- OAB with or without Urge UI

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and appropriate management of patients with urinary incontinence (UI) and overactive bladder, prevention of complications of surgical procedures for UI, and improved quality of life

POTENTIAL HARMS

- Adverse effects of antimuscarinic drugs and catheterisation
- Surgical complications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- While every effort has been made to ensure the accuracy of the information contained within this publication, the publisher can give no guarantee for information about drug dosage and application there of contained in this book. In every individual case the respective user must check current indications and accuracy by consulting other pharmaceutical literature and following the guidelines laid down by the manufacturers of specific products and the relevant authorities in the country in which they are practising.
- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

Key Priorities for Implementation

Assessment and Investigation

- At the initial clinical assessment, the woman's urinary incontinence (UI) should be categorised as stress UI, mixed UI, or urge UI/overactive bladder syndrome (OAB). Initial treatment should be started on this basis. In mixed UI, treatment should be directed towards the predominant symptom.

Expert opinion concludes that symptomatic categorisation of UI based on reports from the woman and history taking is sufficiently reliable to inform initial, non-invasive treatment decisions.

- Bladder diaries should be used in the initial assessment of women with UI or OAB. Women should be encouraged to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days.

Bladder diaries are a reliable method of quantifying urinary frequency and incontinence episodes. The Guideline Development Group (GDG) concluded that a 3-day period allows variation in day-to-day activities to be captured while securing reasonable compliance.

- The use of multi-channel cystometry, ambulatory urodynamics or videourodynamics is not recommended before starting conservative treatment.
- For the small group of women with a clearly defined clinical diagnosis of pure stress UI, the use of multi-channel cystometry is not routinely recommended.
- Multi-channel filling and voiding cystometry is recommended in women before surgery for UI if:
 - There is clinical suspicion of detrusor overactivity.
 - There has been previous surgery for stress incontinence or anterior compartment prolapse.
 - There are symptoms suggestive of voiding dysfunction.

Ambulatory urodynamics or videourodynamics may also be considered in these circumstances.

It has not been shown that carrying out urodynamic investigations before initial treatment improves outcome. Complex reconstructive urological procedures were developed for use in specific urodynamic abnormalities. Hence, the GDG concluded that urodynamic investigations should be used to demonstrate the presence of specific abnormalities before undertaking these procedures. The GDG considered that urodynamic investigations are also of value if the clinical diagnosis is unclear prior to surgery or if initial surgical treatment has failed.

- A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI.

There is good evidence that daily pelvic floor muscle training continued for 3 months is a safe and effective treatment for stress and mixed UI.

- Bladder training lasting for a minimum of 6 weeks should be offered as first-line treatment to women with urge or mixed UI.

There is good evidence that bladder training is an effective treatment for urge or mixed UI, with fewer adverse effects and lower relapse rates than treatment with antimuscarinic drugs.

- Immediate release non-proprietary oxybutynin should be offered to women with OAB or mixed UI as first-line drug treatment if bladder training has been ineffective. If immediate release oxybutynin is not well tolerated, darifenacin, solifenacin, tolterodine, trospium, or an extended release or transdermal formulation of oxybutynin should be considered as alternatives. Women should be counselled about the adverse effects of antimuscarinic drugs.

There is no evidence of a clinically important difference in efficacy between antimuscarinic drugs. However, immediate release non-proprietary oxybutynin is the most cost effective of the available options.

- Pelvic floor muscle training should be offered to women in their first pregnancy as a preventive strategy for UI.

There is evidence that pelvic floor muscle training used during a first pregnancy reduces the likelihood of postnatal UI.

- Sacral nerve stimulation is recommended for the treatment of UI due to detrusor overactivity in women who have not responded to conservative treatments. Women should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation. Life-long follow-up is recommended.

The treatment options for women who have detrusor overactivity and have not responded to conservative therapy are all costly and associated with significant morbidity. There is a stronger body of evidence for the effectiveness of sacral nerve stimulation than for other procedures. Up to two-thirds of patients achieve continence or substantial improvement in symptoms after this treatment.

- Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI where conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.

Many procedures have been described for the treatment of stress UI; although there is no strong evidence of superior effectiveness of any one, the best available data support the use of retropubic mid-urethral tape procedures, colposuspension and autologous rectus fascial sling. Retropubic mid-urethral tape procedures consume fewer hospital resources and are associated with faster recovery than the other two procedures.

- Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women.

The expertise of the surgeon is one of the factors that influence surgical outcomes. The best outcomes are achieved when surgeons and/or their multidisciplinary team have specialist training and regular practice in continence surgery.

A plan for implementation is described in the companion document *Urinary Incontinence in Women, Implementation Advice*. (See the "Availability of Companion Documents" field.)

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 221 p. [960 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Oct

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Women's and Children's Health - National Government Agency [Non-U.S.]

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National Institute for Health and Clinical Excellence (NICE)

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interest are shown in Appendix A of the original full-length guideline document.

GUIDELINE STATUS

This is the current release of the guideline.

Clinical guidelines commissioned by National Institute for Health and Clinical Excellence (NICE) are published with a review date 4 years from the date of publication. Reviewing may begin earlier than 4 years if significant evidence that affects guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Urinary incontinence. The management of urinary incontinence in women. London (UK): National Institute for Clinical Excellence (NICE); 2006 Oct. 36 p. (NICE clinical guideline; no. 40). Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence. The management of urinary incontinence in women. Quick reference guide. National Collaborating Centre for Women's and Children's Health, 2006 Oct. 13 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence. The management of urinary incontinence in women. Pullout. 2006 Oct. 2 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

- Urinary incontinence. Costing template. 2006 Oct. Various p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence. Costing report. Implementing NICE guidance in England. 2006 Oct. 33 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence in women. Slide set. 2006 Oct. 22 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence in women. Implementation advice. 2006 Oct. 21 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Urinary incontinence in women. Audit criteria. 2006 Oct. 14 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1128. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Urinary incontinence: the management of urinary incontinence in women. Understanding NICE guidance. Information for people who use NHS services. National Institute for Health and Clinical Excellence (NICE), 2006 Oct. 11 p. Available from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1129. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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This summary was completed by ECRI on March 30, 2009.

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